Prophylactic tributyrin supplementation in acute pancreatitis

Published: 18-05-2022
Last updated: 05-06-2025

The main objective is to investigate the effect of oral tributyrin on plasma endotoxin in patients with acute pancreatitis.

Ethical review	Approved WMO
Status	Recruitment started
Health condition type	Bacterial infectious disorders
Study type	Interventional research previously applied in human subjects

Summary

ID

NL-OMON56163

Source
ToetsingOnline

Brief title
PARROT

Condition

- Bacterial infectious disorders
- Exocrine pancreas conditions

Synonym
acute pancreatitis; acute pancreatic inflammation

Research involving
Human

Sponsors and support

Primary sponsor: St. Antonius Ziekenhuis
Source(s) of monetary or material Support: Eerste geldstroom (geld van Ministerie van OC&W aan universiteiten),St. Antonius Ziekenhuis

Intervention

- Food (substances)

Keyword: Acute pancreatitis, Tributyrin

Explanation

N.a.

Outcome measures

Primary outcome

The primary endpoint is plasma endotoxin concentration measured 3 days after
 randomisation.

Secondary outcome

Secondary endpoints are toxicity, clinical outcomes, intestinal permeability,
 fecal SCFA concentrations, intestinal microbiota composition and systemic
 inflammatory response parameters (pulse, respiratory rate, temperature and
 white blood cell count), response of peripheral blood mononuclear cells (PBMCs)
 to stimulation with LPS, capacity of PBMCs to phagocytose/kill bacteria (E.
 coli).

Study description

Background summary

Acute pancreatitis (AP) is a common gastrointestinal disorder requiring acute hospitalization. Around 20% of patients that present with acute pancreatitis eventually develop severe complications such as (multiple) organ failure, (peri-) pancreatic necrosis, and secondary infections (i.e. infected necrosis, bacteraemia, pneumonia). The gut, especially the gut microbiome, is likely to play a role in development of infectious complications. Short-chain fatty acids (SCFAs) produced by the gut microbiota, such as butyrate, are known immunomodulators of the host response and exert local beneficial effects on the gut barrier and microbiota. Currently, there are no safe and effective therapies to mitigate disease severity that can be administered in the early phase of pancreatitis. We hypothesize that orally administered tributyrin, a pro-drug of butyrate, might beneficially influence disease progression in acute pancreatitis and may be useful as prophylaxis.

Study objective

The main objective is to investigate the effect of oral tributyrin on plasma endotoxin in patients with acute pancreatitis.

Study design

Phase IIa (Proof of concept) double-blind randomized placebo-controlled food supplement trial.

Intervention

The intervention group receives three times daily 4g micro-encapsulated granules of tributyrin and the control group receives three times daily an equivalent volume of micro-encapsulated vegetable oil (i.e. placebo), for a total of maximum 14 days.

Study burden and risks

The blood sampling at inclusion, and day 3 and 7 of treatment are preferably combined with regular blood sampling. Participants may experience minor discomfort from rectal swabs. Phase 1 studies with oral tributyrin conducted in patients with solid tumors did not report serious adverse events. However, there is a risk of unanticipated adverse events in our target population. An independent data safety and monitoring board (DSMB) will discuss all reported serious adverse events (SAE*s).

Contacts

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Trial sites

Trial sites in the Netherlands

St. Antonius Ziekenhuis
Target size: 52

Reinier de Graaf Groep
Target size: 40

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

acute pancreatitis, defined as two or more of the following criteria:
- abdominal pain
- serum amylas or lipase more than three times the upper limit
- evidence of acute pancreatitis on abdominal CT

Exclusion criteria

-Pancreatitis due to ERCP, malignancy, trauma
-Post-operative pancreatitis
-Intra-operative diagnosis
-Immunocompromised patients (history or current immunosuppressive treatment such as chemotherapy, radiotherapy, longer use of immunosuppressive medication or recent high doses, immunocompromised illness* such as AIDS, leukemia, lymphoma)
-Pregnancy and/or lactation
-Age <18 years old
-History of chronic (MANNHEIM criteria) pancreatitis
- >72 hours since onset of symptoms
- Episode of acute pancreatitis within the last year, or a history of three or

more episodes of acute pancreatitis

Study design

Design

Study phase:	N/A
Study type:	Interventional research previously applied in human subjects
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment started
Start date (anticipated):	12-02-2024
Enrollment:	92
Duration:	3 months (per patient)
Type:	Actual

Medical products/devices used

Product type:	N.a.

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N.a.

Ethics review

Approved WMO

Date:	11-05-2023

Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-12-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-03-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-07-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	30-01-2025
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-05-2025
Application type:	Amendment
Review commission:	MEC-U

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT06147635
CCMO	NL81496.100.22
Research portal	NL-004929